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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/654,545	09/03/2003	William L. Mengeling	27093B-CNT1	3989

23589 7590 10/28/2005
HOVEY WILLIAMS LLP
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EXAMINER

SALIMI, ALI REZA

ART UNIT PAPER NUMBER

1648

DATE MAILED: 10/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/654,545

Applicant(s)

MENGELING ET AL.

Examiner

A R. Salimi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 October 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>9/3/03</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group II (Claims 5-11) in the reply filed on 10/12/2005 is acknowledged.

Priority

An application in which the benefits of an earlier application are desired must contain a specific reference to the earlier filed application(s) in the first sentence of the specification (37 CFR 1.78). This statement should be **updated** as to reflect the latest status of the priority application.

Claim Rejections - 35 USC § 112

Claims 5-11 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: isolating viral RNA is missing, and the method is missing a final determining step to distinguish the attenuated strain verses the virulent strain. This affects the dependent claims. This affects dependent claims 6-11.

Claim Rejections - 35 USC § 112

Claims 5-11 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of differentiating PRRSV attenuated isolate JA-142 from the

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virulent type utilizing NspI restriction enzyme, does not reasonably provide enablement for a general method of differentiating any and all attenuated PRRSV type from the virulent field virus. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims. The disclosure does not provide adequate teaching within the broad scope of claimed invention. The field of virus differentiation is very unpredictable. The disclosure provides teaching that isolate JA-142 exhibits a different pattern than the virulent PRRSV type when restriction enzyme NspI is utilized, namely JA-142 possess two NspI sites, as oppose to one or none at all for the virulent type. However, there are no teachings that whether or not all attenuated PRRSV exhibit this pattern if and when restriction enzyme is used. Consequently, it is not clear whether one of ordinary skill in the art would be able to differentiate between the vaccinated verses non-vaccinated utilizing the claimed method. Absent teaching by the specification one of ordinary skill in the art would be forced to conduct large quantity of undue experimentation to enable full scope of the claimed invention. Absent teaching by the applicants large quantity of false negative would result, since it is not clear whether or not all attenuated virus strains would show the same pattern as JA-142. Additionally, one of ordinary skill in the art would be required to conduct large quantity of experimentation to determine what if any restriction enzyme would render the results envisioned. Therefore, considering large quantity of experimentation needed, the unpredictability of the field, the state of the art, and breadth of the claims, it is concluded that undue experimentation would be required to enable the intended claim. Many of these factors have been summarized at *In re Wands*, 858 F.2d 731, USPQ2d 1400 (Fed. Cir. 1988).

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Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 5, 7-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Wesley et al (WO 97/31652).

The broad limitation of the claimed invention is clearly anticipated by the above-cited reference. Wesley et al taught a method of differentiating PRRSV from a second strain (see the abstract, and the claims 1-4). The cited reference taught differentiation between the field strain and an attenuated strain VR-2332 (see page 9). Additionally, they taught employment of PCR (see pages 6-7).

No claims are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to A. R. Salimi whose telephone number is (571) 272-0909. The examiner can normally be reached on Monday-Friday from 9:00 Am to 6:00 Pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (571) 272-0902. The Official fax number is (571) 273-8300.


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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A. R. Salimi

10/26/2005


ALI R. SALIMI
PRIMARY EXAMINER